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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,328	02/14/2002	Alan E. Kligerman	CD097D4C1	1125
7590 10/02/2003			EXAMINER	
GLAXOSMITHKLINE			WITZ, JEAN C	
Corporate Intellectual Property - UW2220			ART UNIT	
P.O. Box 1539			PAPER NUMBER	
King of Prussia, PA 19406-0939			1651	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,328	KLIGERMAN, ALAN E.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on preliminary amendment A.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10,12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-8, 10, 12, 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by the disclosures of Sherba, Delente et al., or Suzuki (3,795,585).

The cited claim is drawn to a composition containing alpha-galactosidase and a non-toxic ingestible excipient, and specifically the form of the composition is claimed as a liquid. Each of the prior art references teaches compositions containing alpha-galactosidase in an aqueous solution. Recitation of the phrase “an amount of alpha-galactosidase effective to hydrolyze said sugars in-vivo to their simplest absorbable constituents after mixing in the stomach of the mammal ingesting the food” is deemed a recitation of intended use and fails to confer patentability to an old composition.

In the instant case, the pharmaceutical composition is old. It is also well known to package a pharmaceutical composition with instructions on how to use the product. In this case, the claimed “instructions” set forth an intended use of an old product and the nature of the printed matter on the conventional instructions included with the known composition as a kit does not change the composition in any way and does not result in a new or unobvious composition. Nonfunctional descriptive material cannot render patentable an invention that would have otherwise been unpatentable. Cf. *In re Gulack*,

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703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). It is noted at page 5, section B, paragraph 2 of the decision, the court found that "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-8, 10, 12, 14-18, 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Ohara et al. (Sugar Technology Reviews), JP 48-26978, JP 57-144982, Suzuki et al., Lunde, Dey et al. (Advances in Enzymology), Sherba, Delente et al., Olivieri et al. in view of both Solomons et al. references. (references R and S).

Ohara et al. disclose alpha-galactosidase as known to hydrolyze alpha-D-galactoside-linked sugars and states that the enzyme may be utilized as a digestive aid when foods such as beans which contain said sugars have not been previously treated with the enzyme. See page 254. The Japanese references disclose that alpha-galactosidase is known to be used as a digestive medicine. Suzuki et al. teaches that

alpha-galactosidase is known to be used as a pharmaceutical digestive formulation. See col. 1, lines 34-36. Lunde discloses that the digestibility of legumes are deflatulated and their digestibility is improved by the addition of enzymes extracted from pineapple and papaya. The reference identifies the problem, i.e. the absence of alpha-galactosidase in the digestive tract (see col. 1, line 61-col.2, line 6) and states that the enzyme can be added to the food before, during or after cooking and in Example 1, bromelain is added to beans, heated for 5 minutes and consumed. No flatulence or discomfort was reported. At col. 4, lines 52-62, the patent teaches that the composition of bromelain and papain as to non-protease enzymes is similar and per the teaching of Dey et al., papain is known to contain alpha-galactosidase. The Solomons et al. references teach that it is conventional to administer enzymes intended to digest sugars contained in food contemporaneously with the food about to be ingested. Therefore, it would have been obvious to one of ordinary skill in the art to administer alpha-galactosidase contemporaneously with food containing alpha-D-galactoside-linked sugars for the expected benefit of reducing gastric distress.

The references discloses the enzyme as a feed supplement or a feed supplement component for the purpose of increasing energy value of the feed and reducing flatulence in the lower intestine. A feed supplement is mixed with the feed and is therefore eaten at the same time, i.e. contemporaneously, with the feed. Further, as the enzyme and the feed are in contact with each other at the time of ingestion, it is expected that hydrolysis of the sugars is occurring and continues to occur during mixing in the stomach.

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Further, the Solomons abstracts provide more motivation to administer the enzyme contemporaneously with the food.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8, 10, 12, 14-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,989,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill would be aware that the tablets could be pulverized and the contents of the soft gel capsules could be solubilized for those individuals incapable of swallowing tablets or capsules.

Since all of the references cited in this application were cited in the previous application 09/444855, no Form 892 has been included with the application.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-

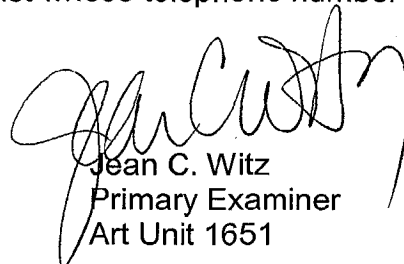
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3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz
Primary Examiner
Art Unit 1651

October 1, 2003